

(PCT Article 36 and Rule 70)

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| Date of submission of the demand | Date of completion of this report |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/001614

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-7 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-3, 5-15 received by this Authority on 02.02.2005
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/4-4/4 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☒ the claims, nos. 4 _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/001614

| Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | |
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| 1. Statement | | | |
| Novelty (N) | Claims | 2, 5-11, 13-15 | YES |
| | Claims | 1, 3, 12 | NO |
| Inventive step (IS) | Claims | 2, 5-11, 13 | YES |
| | Claims | 1, 3, 12, 14-15 | NO |
| Industrial applicability (IA) | Claims | 1-3, 5-15 | YES |
| | Claims | | NO |
| 2. Citations and explanations (Rule 70.7) | | | |
| <p>Document 1: Rochard, E. et al., FEBS Lett, 1989, Vol. 255, No. 1, pages 201 to 204</p> <p>Document 2: Bourne, Y. et al., J. Mol. Biol., 1992, Vol. 227, No. 3, pages 938 to 941</p> <p>Document 3: Hutchens, T.W. et al., Proc. Natl. Acad. Sci. USA, 1991, Vol. 88, No. 8, pages 2994 to 2998</p> <p>Document 4: Mead, P.E. et al., Nucleic Acids Res. 1990, Vol. 18, No. 23, page 7167</p> <p>The inventions set forth in claims 1, 3 and 12 lack novelty and do not involve an inventive step in the light of documents 1 and 2. Documents 1 and 2 set forth a polypeptide containing a Phe-Lys-Asp amino acid sequence with a molecular weight of less than 25kDa, obtained by fragmenting human lactoferrin with a protease.</p> <p>The invention set forth in claim 12 lacks novelty and does not involve an inventive step in the light of documents 3 and 4. Documents 3 and 4 indicate that human or bovine lactoferrin is fragmented with protease then refined, and a polypeptide containing a Phe-Lys-Asp amino acid sequence is isolated and refined.</p> <p>The invention set forth in claims 14 and 15 does not</p> | | | |

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| | <p>involve an inventive step in the light of documents 1 to 4. It would be easy for a person skilled in the art to determine the amino acid sequence of part of the polypeptide set forth in documents 1 to 4, and to produce a synthetic peptide from said amino acid sequence.</p> <p>The inventions set forth in claims 2, 5 to 11 and 13 are not disclosed in documents 1 to 4, and are therefore novel and involve an inventive step. Documents 1 to 4 do not indicate that a polypeptide containing a Phe-Lys-Asp amino acid sequence with a molecular weight of less than 25kDa is obtained by fragmenting lactoferrin with elastase, or that said polypeptide has inflammation-inducing activity, and it would not be easy for a person skilled in the art to conceive of these features in the light of documents 1 to 4.</p> |